

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

**UNITED STATES OF AMERICA *et al. ex  
rel.* ANTONI NARGOL and  
DAVID LANGTON,**

**Plaintiffs,**

**V.**

**DEPUY ORTHOPAEDICS, INC.,  
DEPUY, INC., and  
JOHNSON & JOHNSON SERVICES, INC.,**

## Defendants.

**Civil Action No.  
12-10896-FDS**

**MEMORANDUM AND ORDER ON  
RELATORS' MOTION FOR RECONSIDERATION**

**SAYLOR, J.**

This is a *qui tam* action alleging the submission of false claims to government health-care programs for a defective hip-replacement device. Relators Dr. Antoni Nargol and Dr. David Langton, who are expert witnesses in two related MDL proceedings that involve a similar device, brought suit against defendants DePuy Orthopaedics, Inc., DePuy, Inc., and Johnson & Johnson Services, Inc.<sup>1</sup> The second amended complaint (“SAC”) alleges that DePuy directly submitted and indirectly caused third parties to submit false claims for payments to government health-care programs for the Pinnacle metal-on-metal hip device (“Pinnacle MoM”). According to the SAC, the claims were false because DePuy made numerous misrepresentations to the FDA and surgeons concerning, among other things, the Pinnacle MoM’s failure rates.

On February 1, 2016, the Court unsealed the SAC and granted DePuy's motion to dismiss

<sup>1</sup> For clarity, the defendants will be referred to collectively as “DePuy.”

the relators' 168-page SAC for failure to plead a single false claim, either direct or indirect, with the particularity required by Fed. R. Civ. P. 9(b) and *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13 (1st Cir. 2009) ("*Duxbury I*"). In the same order, the Court also denied the relators' informal and boilerplate request for leave to file a third amended complaint, on the basis of undue delay.

On March 1, 2016, the relators moved for reconsideration of the Court's order pursuant to Fed. R. Civ. P. 59(e) and 60(b)(2) and renewed their request for leave to file a fourth complaint. Despite having three opportunities over the course of four years to satisfy long-established False Claims Act pleading standards, the relators now contend that in the twenty-eight days since the Court's order, they have secured new, previously undiscoverable evidence of false indirect claims.

A motion for reconsideration on the basis of new evidence must be denied where the movant fails to provide a cogent reason for why the evidence was previously undiscoverable. If the evidence should have been discovered previously with appropriate diligence, the evidence is not considered "new." After careful review of the added information in the proposed third amended complaint and the relators' explanations for why it was previously undiscoverable, it appears that the information should have been discovered before the SAC was filed, even with only the most basic investigative diligence. Indeed, the information should have been discovered four years and three complaints ago.

Accordingly, and for the following reasons, the relators' motion for reconsideration will be denied.

## **I. Background**

The facts as alleged in the relators' SAC are recited at length in the Court's February 1,

2016 order. For purposes of understanding the issues involved in their motion for reconsideration, the following abbreviated statement of facts is provided.

On May 18, 2012, the relators filed the original *qui tam* complaint in this case under seal.<sup>2</sup> The Court granted the relators' motion to file an amended complaint on December 2, 2013. On July 29, 2014, the government declined to intervene in this case after conducting its investigation.

On August 12, 2014, Judge Talwani unsealed the case going forward but granted the relators' request to keep the first amended complaint under seal. The relators made that request, in part, because the first amended complaint incorporated confidential DePuy documents that the relators had access to through their work as expert witnesses in two related MDL actions. However, there were standing confidentiality orders in those two MDL actions that prevented the relators from using confidential documents for any reason outside the scope of their expert testimony. *See In re: DePuy Orthopaedics, Inc. ASR Hip Implant Prods. Liab. Litig.*, No. 1:10-md-02197 ("ASR MDL"); *In re: DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, No. 3:11-md-02244 ("Pinnacle MDL").

The relators moved to intervene in the ASR MDL in an effort to modify the confidentiality order. However, the presiding judge denied the relators' motion, concluded that the relators had violated the confidentiality order, and specifically prohibited the relators from using any confidential information that they obtained through their role as expert witnesses in the present FCA case. (Def. Ex. A, Judge Katz Jan. 5, 2015 Order at 7-8) ("If the Court agreed with the intervenors' request, these retained experts would be free to use the knowledge they obtain

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<sup>2</sup> The case was initially assigned to Judge O'Toole, then was reassigned to this judge on August 10, 2012, then was reassigned to Judge Talwani on June 26, 2014, and finally reassigned back to this judge on October 8, 2014.

during this litigation for their own benefit [in the FCA case]. This result is unacceptable . . .”).

With the first amended complaint tainted, this Court granted the relators’ request to file a second amended complaint devoid of any confidential information gleaned from the ASR MDL. That sealed SAC became the operative complaint on June 5, 2015. DePuy moved to dismiss the SAC for failure to meet the pleading requirements of Fed. R. Civ. P. 9(b) and 12(b)(6) on June 26, 2015. Instead of moving to amend, the relators opposed the motion, filed a sur-reply, and litigated the issue during a July hearing. On August 21, 2015, the relators moved to unseal the SAC, but again did not move for leave to amend.

On February 1, 2016, the Court granted DePuy’s motion to dismiss, concluding that the 168-page SAC failed to plead a single direct or indirect false claim with the particularity required by Rule 9(b) and *Duxbury I*. The Court also denied the relators’ informal request to file a fourth complaint on the basis of undue delay.<sup>3</sup>

On March 1, 2016, the relators moved for reconsideration and requested that the Court allow them to file a proposed third amended complaint. According to the relators, they have secured new, previously undiscoverable evidence of indirect false claims involving the Pinnacle MoM.<sup>4</sup>

## **II. Legal Standard**

Amendment or alteration of a judgment is “an extraordinary remedy which should be used sparingly.” *Palmer v. Champion Mortg.*, 465 F.3d 24, 30 (1st Cir. 2006).

The Court has “substantial discretion and broad authority” to grant a motion for reconsideration pursuant to Fed. R. Civ. P. 59(e). *Ruiz Rivera v. Pfizer Pharm., LLC*, 521 F.3d

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<sup>3</sup> The relators did not formally move for leave to amend the SAC. However, in the conclusion of their opposition to DePuy’s motion to dismiss, they requested that leave be freely given should the Court conclude that the SAC did not meet the pleadings standards of Rule 9(b).

76, 81 (1st Cir. 2008). However, a motion for reconsideration will be granted only upon a showing of (1) a “manifest error of law,” (2) new evidence, or (3) a misunderstanding or other error “not of reasoning but apprehension.” *Id.* at 81-82. A Rule 59(e) motion should not be used to “advance a new argument that could (and should) have been presented prior to the district court’s original ruling.” *Cochran v. Quest Software, Inc.*, 328 F.3d 1, 11 (1st Cir. 2003). Nor is a Rule 59(e) motion an appropriate means to “repeat old arguments previously considered and rejected.” *National Metal Finishing Co. v. Barclays American/Commercial Inc.*, 899 F.2d 119, 123 (1st Cir. 1990).

Rule 60(b) provides a mechanism for setting aside a judgment in certain circumstances. The rule provides, in relevant part, that a court “may relieve a party or its legal representative from a final judgment, order, or proceeding for the following reasons . . . (2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b).” Fed. R. Civ. P. 60(b)(2). “Because Rule 60(b) is a vehicle for extraordinary relief, motions invoking the rule should be granted only under exceptional circumstances.” *Davila-Alvarez v. Escuela de Medicina Universidad Central del Caribe*, 257 F.3d 58, 64 (1st Cir. 2001) (internal quotation marks omitted).

### **III. Analysis**

The relators contend that their motion for reconsideration should be granted because they have discovered new, previously undiscoverable evidence of purportedly false indirect claims.

A Rule 59(e) motion brought on the basis of new evidence “must be denied where the ‘new evidence’ consists of information that, in the exercise of due diligence, could have been

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<sup>4</sup> The relators style their motion as a motion for reconsideration. The Federal Rules of Civil Procedure do not expressly recognize post-judgment motions for reconsideration. Accordingly, the Court will treat the relators’ motion under the standards of Fed. R. Civ. P. 59(e) and 60(b)(2).

presented earlier.” *In re Genzyme Corp.*, 2012 WL 6674483, at \*2 (D. Mass. Dec. 21, 2012), *aff’d sub nom. In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31 (1st Cir. 2014) (citing *Emmanuel v. International Broth. of Teamsters, Local Union No. 25*, 426 F.3d 416, 422 (1st Cir. 2005)). “At the very least the [moving party] must put forth a ‘cogent reason’ as to why this evidence could not have been offered at an earlier stage of the proceedings.” *Id.* (quoting *Fisher v. Kadant*, 589 F.3d 505, 513 (1st Cir. 2009)). In short, evidence is not “new” if the underlying facts were previously discoverable with appropriate diligence. *See Biltcliffe v. CitiMortgage, Inc.*, 952 F. Supp. 2d 371, 384 (D. Mass. 2013).

A party moving for relief from judgment on the basis of newly discovered evidence under Rule 60(b)(2) “‘must at the very least, offer a convincing explanation as to why he could not have proffered the crucial evidence at an earlier stage of the proceedings.’” *Fisher*, 589 F.3d at 513 (quoting *Karak v. Bursaw Oil Corp.*, 288 F.3d 15, 19-20 (1st Cir. 2002)).

The parties do not dispute that the evidence presented in the relators’ proposed third amended complaint is new, in the sense that it was not pleaded in the SAC. However, DePuy contends that the evidence of purportedly false indirect claims is not new because the relators could have presented it earlier if they had conducted their investigation with due diligence. The relators appear to present two principal explanations for why the evidence was previously undiscoverable, even with the appropriate level of diligence. First, they contend that the MDL confidentiality orders prevented them from pleading in the SAC information that they had obtained from those proceedings. Second, they contend that the sealed status of the SAC in this proceeding hindered their ability to investigate false claims and obtain information from MDL plaintiffs’ counsel, surgeons, and Pinnacle MoM patients themselves. Specifically, they contend

that the MDL plaintiffs' attorneys would not speak with them because the SAC in this case remained under seal.

After careful consideration of the proposed third amended complaint and the relators' two explanations, it appears that the relators' "newly discovered" evidence should have, with the appropriate investigative diligence, been discovered and presented earlier in the proceeding. Even relying only on publicly available information and basic investigative strategies, the relators could have—indeed, should have—discovered and presented the "new" evidence not only in their first or second amended complaints, but also in their original complaint filed four years ago.

The analysis begins with the relators' argument that the MDL confidentiality orders hindered their ability to discover information about false claims. It is important to note that those orders appear to be still in effect; the relators were, and continue to be, prohibited from using confidential information that they obtained in their role as experts in the MDL proceedings. Accordingly, any new information in the proposed third amended complaint has not suddenly become discoverable because of changes in the MDL confidentiality orders.

Furthermore, the relators' argument fails to observe the critical distinction between the confidential documents themselves, the use of which is prohibited, and the facts that underlie those documents. The confidentiality orders prevent the relators from using confidential DePuy documents that they obtain through the MDL; they do not prevent the use of any underlying facts. Furthermore, the relators could have used basic investigative tactics to obtain those underlying facts without violating the confidentiality orders. Indeed, much of the investigative legwork had already been completed for the relators by thousands of MDL plaintiffs and their attorneys in their publicly available complaints. Accordingly, the existence of the confidentiality

order is not a sufficiently cogent or convincing reason as to why the evidence was previously undiscoverable.

The relators' second argument—that the SAC's sealed status prevented them from discovering the newly-pleaded evidence of allegedly false claims—is equally unpersuasive. Before addressing the actual substantive reasons why the seal is not a convincing explanation, the Court will make two background observations.

First, the SAC was sealed, and remained sealed, at the relators' request because they had previously violated the ASR MDL confidentiality order. In essence, the relators requested that the Court seal the SAC as a backstop to prevent the disclosure of DePuy's confidential information, and to avoid being reprimanded by Judge Katz for a second time. It is unclear why the relators did not simply review the SAC carefully before filing in order to ensure that it did not contain any confidential information.

Second, while the Court did not unseal the SAC until it ruled on DePuy's motion to dismiss in February 2016, the relators did not move to unseal it until August 2015, after DePuy filed its motion to dismiss. Moreover, the relators did not move to amend the SAC at that time. Instead, they vigorously opposed DePuy's motion, evidently satisfied to accept the risk that the Court would find the SAC's allegations insufficient under the well-established pleading standards required by Rule 9(b) and *Duxbury I*. *See Fisher*, 589 F.3d at 513 (noting that plaintiffs' decision to wait to "seek leave to amend their complaint based on [supposedly new] evidence" until after the district court entered judgment was "a strategic choice," and the fact that their choice "backfired is not a ground for relief from judgment").<sup>5</sup>

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<sup>5</sup> The relators repeatedly suggest throughout their motion for reconsideration that this Court's decision in *United States ex rel. Leysock v. Forest Labs, Inc.*, 55 F. Supp. 3d 210 (D. Mass. 2014) established new, heightened Rule 9(b) pleading standards for cases brought pursuant to the FCA. The Court disagrees. In *Leysock*, the Court applied the well-established standard explained by the First Circuit in *Duxbury I*, which was issued in 2009. *See id.*



In any event, the relators assert, without explanation, that the MDL plaintiffs' attorneys would not speak to them unless the SAC was unsealed. But even accepting that bald assertion as true, the relators do not explain why they did not utilize other basic investigative means to obtain the relevant facts. For example, it is unclear why the relators could not have contacted orthopedic surgeons—at least some of whom should have been well-known to the relators, as orthopedic surgeons themselves—who had implanted the Pinnacle MoM. If they had contacted the surgeons, some simple questions that did not violate patient privacy rights might have provided some basic answers.<sup>6</sup> Again, the underlying facts of potentially false claims were not unavailable simply because the SAC remained under seal.

Moreover, even assuming that the relators could not investigate the underlying facts of potentially false claims by contacting MDL plaintiffs' attorneys or surgeons, there were hundreds, if not thousands, of publicly available complaints filed in the MDL. The relators do not explain why they failed to review those complaints at the outset of this litigation to find situations where the federal government had paid for a Pinnacle MoM implant.

To highlight just two examples, in their motion for reconsideration the relators contend that they did not know that Patient 4, identified in their proposed third amended complaint, was a veteran—and thus likely to have his hip-replacement device paid for by the federal

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at 219 (quoting *Duxbury I*, 579 F.3d at 30) (noting that the *Leysock* relator identified “one of defendants’ sales representatives, the doctor, and the patient (the who), the specific misrepresentations made by the defendants (the what), time periods and locations (the where and when), and the filing of the false claims themselves”). Moreover, and in any event, it is disingenuous for the relators to suggest that the Court applied its own unique pleading standards in considering DePuy’s motion to dismiss. The Court did what it always must do: apply the law dictated by the First Circuit, which in this case is *Duxbury I*. In ruling on DePuy’s motion, the Court discussed *Leysock* very briefly, and only because both parties spent significant portions of their briefs comparing *Leysock* to the relators’ allegations here.

<sup>6</sup> One would expect a non-exhaustive list to include questions such as: Have you implanted a DePuy Pinnacle MoM device? When? How old was the patient? How was the device paid for? What types of marketing materials did you receive from DePuy? Did those affect your decision to use the Pinnacle MoM for your patient? What were the results of the surgery?

government—until he testified during a public MDL hearing on February 10, 2016. But the relators fail to mention that Patient 4 filed his complaint on August 5, 2011, nine months before the relators filed their *original* complaint in this action, and that the complaint remained publicly available for the entire four-year period leading up to DePuy’s motion to dismiss. In that complaint, Patient 4 identifies himself as a “30 year U.S. Navy veteran” who received a total hip replacement on January 19, 2005. (Def. Ex. I ¶ 35). The complaint identifies the exact type of device he was implanted with: a Pinnacle MoM with an Ultamet liner. (*Id.*)<sup>7</sup> A diligent investigator might have attempted to contact Patient 4’s counsel before filing the initial, much less the third, complaint in this action. Another publicly available MDL complaint, filed on November 14, 2011, identifies a plaintiff who was implanted with a “Pinnacle Hip” on October 20, 2009 at a VA hospital in Seattle, Washington by Dr. Howard Chansky. (Def. Ex. H ¶ 36). A diligent investigator might have attempted to contact Dr. Chansky or the plaintiff’s counsel to determine whether the plaintiff was implanted with a Pinnacle MoM device (as suggested by paragraph 28 of his complaint), and whether his device was paid for by the federal government (as suggested by the fact the procedure occurred in a VA hospital).

As noted in the Court’s earlier order, the SAC was essentially a products-liability complaint, not an FCA complaint. Despite access to large quantities of publicly available MDL complaints and related information, the 168-page SAC failed to plead with sufficient particularity even a *single* false claim. In fact, after four years and three complaints, many of the SAC’s allegedly false claims did not even refer to the Pinnacle MoM, the only device that is at issue in this case. If there is any cogent, convincing reason for why the information in the

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<sup>7</sup> For an explanation of the Ultamet liner’s significance to the particularity requirements of Rule 9(b) in this case, refer to the Court’s February 1, 2016 order at pages 32 through 34.

relators' proposed third amended complaint was previously undiscoverable, the relators have failed to provide it in their motion for reconsideration.

In sum, the relators' motion for reconsideration will be denied under Fed. R. Civ. P. 59(e) and 60(b)(2) for failure to provide a cogent, convincing explanation as to why the "new" evidence was previously undiscoverable.

**IV. Conclusion**

For the foregoing reasons, the relators' motion for reconsideration of the Court's denial of leave to amend the complaint is DENIED.

**So Ordered.**

Dated: April 11, 2016

/s/ F. Dennis Saylor  
F. Dennis Saylor IV  
United States District Judge